

### **REMARKS**

Favorable reconsideration and allowance of the present application are respectfully requested in view of the foregoing amendments and the following remarks.

Currently, claims 35-68 are pending in the present application, including independent claims 35, 48, 56, and 68. Claims 1-34 are being cancelled in this paper.

Independent claim 1, for instance, is directed to a diagnostic device comprising a test surface comprising a binder applied thereon. The diagnostic device further comprises a means for inducing a pressure differential on a sample to direct the sample to the test surface and also to clear an unreacted portion of the sample from the test surface by directing the unreacted portion of the sample past the test surface to a chamber for containing the unreacted portion of the sample so that the test surface can be analyzed.

In the Office Action, original independent claims 1, 13, and 22 were all rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,677,133 to Oberhardt. Oberhardt is directed to a method for performing an affinity assay comprising: (1) contacting a sample to be assayed for the presence of an analyte with a dry reagent containing the analyte bound to a reaction cascade initiator, an antibody reactive with the analyte, and magnetic particles, to form an assay mixture in a reaction chamber; (2) incubating the assay mixture; (3) applying an oscillating or moving static magnetic field to the assay mixture; (4) activating the reaction cascade initiator to initiate a reaction cascade; (5) monitoring the response of the magnetic particles to the oscillating or rotating magnetic field to provide a time varying signal; and (6) determining the analyte concentration of the sample by analysis of the time varying signal. (Col. 4,

lines 48-64). Oberhardt describes carrying out its affinity assay method using a reaction slide such as the slides pictured in Figures 1-4.

However, Oberhardt does not teach a diagnostic device according to Applicants' claims that includes (a) a test surface comprising a binder applied thereon; and (b) a means for inducing a pressure differential on a sample (1) to direct the sample to the test surface *and* (2) to clear an unreacted portion of the sample from the test surface by directing the unreacted portion of the sample past the test surface to a chamber for containing the unreacted portion of the sample. By way of example only, Applicants' specification and Figures illustrate embodiments of such a diagnostic device, wherein a syringe 50 is employed as the means for inducing a pressure differential on the sample. In these embodiments, the means (syringe 50) is used to direct sample 60 to test surface 42. The means (syringe 50) is also used to clear an unreacted portion of the sample from test surface 42 by directing the unreacted portion of the sample past test surface 42 to cylindrical chamber 56 for containing the unreacted portion of the sample. No such diagnostic device is taught by Oberhardt.

In Oberhardt, the reaction slides may be equipped with some sort of "means" that may be capable of inducing a pressure differential on a sample. For example, with regard to Figure 3, Oberhardt states that a sample to be analyzed may be added to the reaction slide by a means such as a micropipette, a pipette, a leur-tipped syringe, or a capillary tube. (Col. 6, lines 30-38). And with regard to Figure 4, Oberhardt states that the sample to be analyzed may be moved from the sample well 64 to the reaction chamber 62 using a vacuum source placed over a vent at the reaction chamber or using pressure at the inlet to the sample well. (Col. 5, lines 16-20; col. 6, lines 45-61).

However, any such "means" in Oberhardt does not both (1) direct a sample to a test surface having a binder applied thereon and (2) clear an unreacted portion of that sample from that test surface by directing the unreacted portion of the sample past the test surface to a chamber for containing the unreacted portion of the sample so that the test surface can be analyzed.

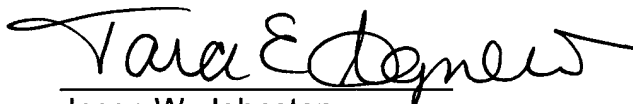
Simply put, in Oberhardt, the reaction slide is set up so that any sample to be analyzed merely travels from sample well 64 to the reaction chamber (e.g., reaction chamber 62 in Figures 1-4 or reaction chambers 109, 110, 111, and 112 in Figure 11). When the sample in Oberhardt reaches the reaction chamber, the entire sample is contacted with the dry reagent to form an assay mixture, and the other steps in the assay method (e.g., incubating the assay mixture, applying a magnetic field to the assay mixture, activating the reaction cascade initiator, monitoring a response using optical means, and ultimately determining the concentration of an analyte) all take place while the assay mixture *remains in the reaction chamber*. (Col. 5, lines 9-11 and 48-63). Nothing in Oberhardt teaches or in any way suggests equipping a diagnostic device with a means for inducing a pressure differential on a sample, wherein the means both (1) directs a sample to a test surface having a binder applied thereon *and* (2) clears an unreacted portion of that sample from that test surface by directing the unreacted portion of the sample past the test surface to a chamber for containing the unreacted portion of the sample so that the test surface can be analyzed. Thus, Applicants respectfully submit that new independent claims 35, 48, 56, and 68 patentably define over Oberhardt.

Accordingly, for at least the reasons set forth above, Applicants respectfully submit that the present claims patentably define over all of the prior art of record. It is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Snay is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,

DORITY & MANNING, P.A.



Jason W. Johnston  
Registration No.: 45,675

Tara E. Agnew  
Registration No.: 50,589

DORITY & MANNING, P.A.  
P.O. Box 1449  
Greenville, SC 29602-1449  
Phone: (864) 271-1592  
Facsimile: (864) 233-7342

Date: 4/15/2005